III. REMARKS

A. Status of the Claims

Claims 1-2, 4-5, 7-15, 18 and 21 have been deleted without prejudice. Claims 3, 6, 16-17 and 19-20 have been amended. New claims 22-33 have been added.

Support for the amendment to claim 3 can be found throughout the original specification as filed, e.g., page 10, line 15; page 12, line 15; and original claim 11.

Support for the amendment to claim 19 can be found throughout the original specification as filed, e.g., page 8, lines 12-22; page 10, line 15; page 12, line 15; and original claim 11.

Support for new claims 22 and 23 can be found throughout the original specification as filed, e.g., page 5, line 10; and original claim 6.

Support for new claim 24 can be found throughout the original specification as filed, e.g., page 11, line 16.

Support for new claim 25 can be found throughout the original specification as filed, e.g., page 17, lines 1-3.

Support for new claims 26-28 can be found throughout the original specification as filed, e.g., page 5, lines 18-24.

Support for new claim 29 can be found throughout the original specification as filed, e.g., page 7, lines 19-26.

Support for new claims 30-32 can be found throughout the original specification as filed, e.g., page 9, lines 18-20.

Support for the new claim 33 can be found throughout the original specification as filed, e.g., page 10, line 15; page 12, lines 6-15; and original claims 1 and 11.

It is respectfully submitted that no new matter has been added by virtue of these amendments.

B. Rejection of Claims 1-20 under 35 U.S.C. § 103(a)

The Examiner maintained the rejection of Claims 1-20 under 35 U.S.C. §103(a) as being unpatentable over W.I.P.O. Publication No. WO 88/02342 to Eek (hereinafter

"Eek"), in view of the United States Patent No. 6,365,184 to Depui *et al.* (hereinafter "Depui").

In the present office action, the Examiner stated that "applicant's arguments [in response to the previous office action] are based upon a narrow interpretation of both the claims and the prior art," and "[i]t is the position of the [E]xaminer that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art." (citation omitted).

Specifically, the Examiner notes that "even non-preferred embodiments constitute prior art, as prior art is relevant for all that it contains," and Depui "merely recites what is already known in the art." The Examiner further states that the "disclosure in Depui et al. does not explicitly state whether or not the lack of effectiveness in separately administering a non-steroidal anti-inflammatory drug and a proton inhibitor also considers the benefits provided by an effective packaging system," and therefore, Depui et al. "does not explicitly teach away from the [E]xaminer's interpretation and combination of the prior art." (Emphasis Added)

Initially, it is noted that claims 1-2, 4-5, 7-15, 18 and 21 have been deleted without prejudice. With respect to amended claim 3, it is submitted that the cited art, either taken alone or in combination, do not teach or suggest all of the limitations of amended claim 3 as presented below:

> 3. A drug packaging system comprising packaging material comprising therein combined prescription drug therapy comprising:
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> unit dosage forms containing lansoprazole or a pharmaceutically acceptable salt thereof;
>
> unit dosage forms containing naproxen or a pharmaceutically acceptable salt thereof;
>
> a blister package comprising: a) rupturable substrates b) a layer forming blisters over each rupturable substrate; wherein each of the blisters contains one of said unit dosage forms.

With respect to Depui, the Examiner's attention is specifically directed to column 2, lines 37-40, which states "[t]he present invention now provides new oral dosage forms comprising two or more different active substances combined in one fixed unit dosage form, preferably a tablet." (*emphasis added*).

In contrast, WO 88/02342 (hereinafter "Eek") which is directed to a drug pack states at page 1, line 32 to page 2, line 9 that "[i]t is well known to provide drugs as a combination preparation wherein each dosage unit e.g., tablet, contains a plurality of active substances," and "[c]ombination preparations are however frequently connected with limitations and drawbacks which causes them often not to provide the best possible treatment." Eek then lists a number of problems associated with a tablet containing a plurality of active substances (e.g., different patients may require different combinations of substances of different dosages of the various substances, simultaneous administration at each dosage time may not be desirable, etc.). Eek asserts that "when treatment with a plurality of drugs is desired . . . a combination pack assembled from two or more packs" may be prepared. In such a combination pack, the drugs are in separate unit dosage forms and not a fixed unit dosage form (a single dosage form containing two or more active substances as described in Depui).

It is submitted that Depui is directed to two or more active substances in a fixed unit dosage form and Eek describes a drug pack for the use of plurality of drugs in separate unit dosage forms. Therefore, it is respectfully submitted that these references are not properly combinable.

Furthermore, the Examiner is reminded that:

> "[a] prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference would be discouraged from the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." See *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998).

Therefore, it is respectfully submitted that Depui teaches away from the present invention in column 2, lines 36-38, by stating that "administration of two or even more

different tablets to the patient is not convenient or satisfactory to achieve the most optimal results."

It is respectfully submitted that in view of the Depui patent, one of ordinary skill in the art would not be led to administer active substances which are combined in a fixed unit dosage form in separate unit dosage forms as Depui describes administration of two or more tablets to a patient as not convenient or satisfactory to achieve the most optimal results. It is respectfully submitted that in view of Depui, one of ordinary skill in the art there would not be motivated to keep two drugs in two separate dosage forms as recited in the present claims and would be discouraged from this path.

Further, it is noted that the Examiner must explain reasons why one of ordinary skill in art would have been motivated to select references and to combine them to render the claimed invention obvious. See *In Re Lee*, 61 USPQ2d 1430, (Fed. Cir. 2002). Also, the factual question of motivation to select and combine references is material to patentability, and cannot be resolved on subjective belief and unknown authority. *Id.*

It is respectfully submitted that the Examiners' motivation to combine the cited references as asserted in the previous Office Action is based on subjective belief and unknown authority. An alleged motivation to arrive at the undesirable result of Depui (separate dosage forms) is no motivation at all.

In the Office Action, the Examiner also stated that what is being claimed is "a packaging system, not a drug combination," and "[t]he effectiveness of the packaging system is neither limited nor enhanced in any way by the selection of specific types of solid unitary dosage forms to be included in the instantly claims packaging system . . . ."

In response, the Examiner is reminded that limitations in a claim following the word "comprising" are limitations that must be considered in patentability analysis. Therefore, the recitation of lansoprazole and NSAID (e.g., naprosyn) are limitations of the claimed packaging system which must be considered by the Examiner.

Dependent Claims

The art relied upon by the Examiner also does not teach or suggest the invention as recited in dependent claims to claim 3, which include:

(i) the limitation of dependent claim 6 which further recites "...wherein each unit dosage form is independently selected from the group consisting of a tablet, capsule, gel cap, and a caplet.";

(ii) the limitation of dependent claim 16 which further recites "...wherein said system comprises unit doses for up to 28 days.";

(iii) the limitation of dependent claim 17 which further recites "...wherein said system comprises unit doses for 7-14 days.";

(iv) the limitation of dependent claim 22 which further recites "...wherein the unit dosage forms containing lansoprazole are capsules";

(v) the limitation of dependent claim 23 which further recites "...wherein the unit dosage forms containing naproxen are tablets";

(vi) the limitation of dependent claim 24 which further recites "...wherein the unit dosage forms containing lansoprazole comprise 15 mg lansoprazole";

(vii) the limitation of dependent claim 25 which further recites "...wherein the unit dosage forms containing naproxen comprise 500 mg naproxen";

(viii) the limitations of dependent claims 26-28 and 30-32 directed to the recited indicia, and

(ix) the limitation of dependent claim 29 which further recites "...wherein one unit dosage form of lansoprazole or pharmaceutically acceptable salt thereof is suitable for once daily dosing.";